**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Application No. | : 09/631,638 | Confirmation No.: 8662 |
| First Named Inventor | : Kevin M. Moore | |
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| TC/A.U. | : 1651 | |
| Examiner | : David M. Naff | |
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Pittsburgh, Pennsylvania

Mail Stop: RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. 1.132**

I, Kevin Moore, hereby declare and state as follows:

1. I am a co-inventor of the invention as claimed in the above-referenced patent application (the "Subject Application").

2. I have reviewed Subject Application, including the claims and specification thereof, and understand the contents.

3. Example 1 of the Subject Application reads as follows:

> A fermentation broth was prepared as described in U.S. Patent No. 5,834,231 containing 84 g/L 2-keto-l-gulonic acid, 4 g/L sorbose and 136 g/L total dry solids and spray dried on a high pressure nozzle sprayer (APV Americas; Tonawanda, New York). The feed was preheated to 170 °F, and dried with a 495 °F inlet and a 198 °F outlet temperature. A total of 8 gallons of feed was dried to give 10.2 lbs. of dried product as 8% moisture.

25 g of the spray dried product was slurried into 250 ml of anhydrous methanol. 3.2 ml of sulfuric acid was added to the solution over 20 minutes while stirring. The slurry was stirred for am additional 60 minutes, filtered and the solids washed with 150 ml of additional methanol. The product filtrate of 320 ml contained 35 g/L 2-keto-l-gulonic acid and 1.7 g/L of 2-keto-l-gulonic acid methyl ester. The cake of 12 grams contained 3.8% 2-keto-l-gulonic acid and 0.4% 2-keto-l-gulonic acid methyl ester, for a yield of 96%.

4. The fermentation of Example 1 was performed to produce a fermentation broth comprising both the organic acid and the biomass. The fermentation broth was subsequently spray dried without filtering to remove biomass, therefore the dried product contained substantially all the biomass produced in the fermentation. Example 1 provides an embodiment of the process as presently claimed.

5. U.S. Patent No. 5,834,231 (the "'231 patent") describes a process for the production of 2-keto-l-gulonic acid by the fermentation conversion of L-sorbose and/or sorbitol. The patent further relates to novel bacterial strains useful in this process.

6. In the subject application, the Examiner has rejected the claims of the application as being unpatentable under 35 U.S.C. 103(a) as being unpatentable over Dumpelman (United States Patent No. 5,852,211) in view of Bott et al (European Patent No. 0 174 624).

7. As stated in the Declaration of Kevin Moore Under 37 C.F.R. §1.132 executed on August 18, 2003 (the "Previous Declaration"), I have read and understand Dumpelman et al. and an English translation of Bott et al. (the "Cited References") Neither of the Cited References disclose a process in which the fermentation broth is dried without first performing a filtration step. In addition, Dumpelman et al. teaches away from the filtering prior to crystallization by stating that the object of the invention is to permit in the simplest possible manner the conversion of the sodium salt of 2-keto-L-gulonic acid, which is present in an aqueous, non-purified

fermentation broth, into free 2-keto-L-gulonic acid in alcoholic solution in high yield and with high purity. For these reasons and the reasons set forth in the Previous Declaration, one skilled in the art would have no reasonable expectation of success of producing an organic acid by drying the fermentation broth without prior filtration of biomass.

8. Example 1 of the Subject Application demonstrates the method of the claimed invention comprising conducting a fermentation to produce a fermentation broth, wherein the fermentation broth comprises an organic acid and microbial biomass, drying the fermentation broth to obtain an organic acid-containing dried product, wherein said drying occurs without prior removal of said microbial biomass from the organic acid-containing fermentation broth. The dried product may then be added to a lower alcohol in the presence of an acid, wherein said acid can be any acid which allows for selective recovery of the desired organic acid. A subsequent step is removing insolubles to obtain an organic acid, wherein the insolubles include the microbial biomass.

Specifically, Example 1 describes a process for the production of 2-keto-L-gulonic acid. The fermentation of Example 1 was prepared as described the '231 patent to produce a fermentation broth comprising an organic acid and microbial biomass. The fermentation was conducted in two steps as described in the '231 patent. As described in col. 5, lines 39-56, Strain ATCC 621 was used to convert sorbitol to sorbose. The fermentation included, as described in col. 6, additional components added to the medium including supplemental carbon sources (mannitol), nitrogen sources (Hysoy T and 10% corn steep liquor) and trace nutrients (Niacinamide, Thiamine, Pantothenic Acid, and Para amino benzoic acid). After conversion of sorbitol to sorbose the medium is pasteurized. The sorbose was then

converted to 2-keto-L-gulonic acid as indicated in column 6, lines 42-58. In the case of Example 1, the medium was inoculated with strain ADM 115-172, a mutant variant of NRRL B-21627. The conversion of sorbose to 2-keto-L-gulonic acid was aided by a "helper" strain of B. Lichenformis (ADM B102) as described in column 7, lines 15-38. Conversion of sorbose to 2-keto-L-gulonic acid is at a pH of 6.5, a temperature of 30°C with 1.5 vol./vol/min of air and a 275 rpm fermenter agitator speed for about 60 hours to prepare the fermentation broth comprising the organic acid and the microbial biomass. The fermentation broth comprised, as indicated in Example 1, 84 g/l 2-keto-L-gulonic acid, 4g/l sorbose and 136 g/l total dry solids including the microbial biomass ("whole fermentation broth").

After the whole fermentation broth was prepared as described above, the whole fermentation broth was dried to obtain an organic acid-containing dried product, wherein the drying occurred without prior removal of the dry solids or the microbial biomass from the whole fermentation broth. The dried product was then further processed, as described in Example 1, by adding the dried product to a lower alcohol, anhydrous methanol, in the presence of an acid, sulfuric acid, finally removing the microbial biomass from the 2-keto-L-gulonic acid. The process as described was subsequently repeated and enables one skilled in the art to conduct the claimed invention.

9. I further declare that all statements made herein are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of

Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any registration resulting therefrom.

Kevin M. Moore

April 8, 2004
Date